

**On-Site Evaluation of the US EPA Region 10
Drinking Water Laboratory Certification Program**

by the

**Office of Ground Water and Drinking Water
Technical Support Center**

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

CINCINNATI, OH 45268

Introduction

The “Manual for the Certification of Laboratories Analyzing Drinking Water” (MCLADW, Fifth Edition, 2005, EPA 815-R-05-004), requires the Office of Ground Water and Drinking Water (OGWDW) to “review the Regional drinking water certification programs and evaluate the resources and personnel available in each Region to carry out the certification program.” Paper reviews in the form of questionnaires are done annually with on-site reviews conducted triennially. The on-site assessment is conducted to assess the adherence of the United States Environmental Protection Agency (EPA) Regional Certification Authority to the requirements of the MCLADW, Chapters I – III. Michella Karapondo and Glynda Smith of the Technical Support Center (TSC) conducted a Quality System Assessment (QSA) of the Region 10 Drinking Water Laboratory Certification Program on October 6-7, 2010 at the Region 10 laboratory in Port Orchard, WA. The QSA included a review of the Region 10 laboratory certification program documents along with discussions with members of the Region 10 laboratory certification team, including Stephanie Harris and Gerald Dodo. Opening and closing briefings were well attended by Region 10 laboratory certification team members and management, including the Region 10 Laboratory Director, Dr. Barry Pepich.

Quality and Timeliness of State Laboratory Audits

Principal State Laboratory (PSL) audits for Chemistry, Microbiology and Radiochemistry are to be conducted on a 3-year cycle as described in the MCLADW. Along with PSL audits, assessment of the state laboratory certification program should be performed, as outlined in Chapter III of the MCLADW. The last dates audits were performed of the PSLs and drinking water laboratory certification programs for the states in Region 10 are shown in Table 1. For completeness, the Spokane Tribe is also included. Commercial laboratories acting as PSLs and other State laboratories are identified in italics.

The Region 10 certification program is current on all PSL audits and certification program reviews. Region 10 also performs the audits of commercial laboratories acting as part of the PSL network for states, with the exception of the two NELAP accredited laboratories, LabCor and Columbia Analytical. The OGWDW assessment team appreciates the amount of resources it takes for Region 10 to maintain this schedule for the number of laboratories in the PSL networks for the states, as well as the distances the Region 10 team has to travel to perform these audits.

Region 10 is commended for maintaining a highly qualified staff with appropriate technical expertise on the laboratory certification team. All of the Region 10 laboratory certification team members are currently bench analysts who regularly work in the Region 10 laboratories. This highly qualified team is very familiar with the drinking water methods and is able to provide valuable technical assistance to the PSLs and state certification officers (COs). The audit reports are very well written, and clearly state the findings and recommendations for each area audited. After corrective actions from the laboratories are deemed acceptable to Region 10, the Region 10 Certification Authority, Joyce Kelly, sends a letter to each PSL clearly stating the methods and contaminants for which the laboratory is certified. The letter also gives the laboratory a time frame for the next audit.

TABLE 1 Assessment Dates of Region 10 States

State/Tribe	Date of Last Assessment of States' Laboratory Certification Program	Date of Last Chemistry Audit	Date of Last Microbiology Audit	Date of Last Radiochemistry Audit
Alaska	Alaska Department of Environmental Conservation (ADEC) Environmental Health Laboratory: August 2009	<i>Utilizes Oregon DEQ and Columbia Analytical Services (NELAP Accredited)</i>	ADEC EHL: August 2009	<i>Utilized Washington Public Health Laboratory, which has since withdrawn request for certification</i>
Idaho	Idaho Bureau of Laboratories: October 2008	Idaho Bureau of Laboratories: October 2008	Idaho Bureau of Laboratories: October 2008	<i>Idaho Bureau of Laboratories: October 2008, has withdrawn request for certification.</i>
Oregon	TNI AB Evaluation of Oregon Laboratory Accreditation Program (ORELAP): March 2009	Oregon Department of Environmental Quality and Oregon Department of Agriculture: August 2008	Oregon Public Health Laboratory: June 2008	No PSL available for radiochemistry
Washington	Washington Department of Ecology: 2007 2010 program audit is scheduled October 25-26	<i>Utilizes Edge Analytical (September 2007); Water Management Laboratories (April 2006); LabCor (NELAP Accredited, no files); Columbia Analytical (NELAP Accredited, no files)</i>	Washington Public Health Laboratory: January 2008	Washington Public Health Laboratory: January 2008 <i>Has withdrawn request for certification</i>
Spokane Tribe			Spokane Tribe: 2009	

The OGWDW assessment team noted that there is no PSL coverage for radiochemistry in Region 10. Audits of the Region 10 radiochemistry PSLs were being conducted by the CSC contractor through TSC, so the assessment team was aware of this situation. Both Idaho and Washington have withdrawn requests for drinking water certification for radiochemistry. Washington Public Health Laboratory does still have radiochemistry facilities. Region 10 is working with the states to develop a plan for radiochemistry drinking water coverage. TSC could provide audit support for oversight of a commercial laboratory acting as the radiochemistry PSL, or the Region 10 states could select a NELAP accredited commercial radiochemistry laboratory and use the NELAP accreditation as basis for a Regional determination that the lab is appropriate. None of the Region 10 states have access to laboratories capable of performing asbestos analyses, as required by 40 CFR 142.10. Region 10 is working with the states to solve this issue.

The OGWDW assessment team also reviewed the Region 10 Standard Operating Procedure (SOP) titled "On-Site Evaluation of State Principal and Tribal Laboratories for SDWA Certification" and had no findings regarding this document. The SOP clearly defines the roles and responsibilities of the PSL audit team, procedures concerning laboratory and Region 10 responsibilities for PT studies, the on-site assessment procedure, timeframes for issuing certification status, and record management procedures. Region 10 is commended for producing a clear, well-defined SOP for assessing the PSLs in the region.

Reviews of State Certification Programs

EPA Regional offices typically review state certification programs at the same time the state PSL on-site evaluation is conducted, on a triennial basis. Region 10 follows this practice, with the exception of Oregon's Oregon Laboratory Accreditation Program (ORELAP), which is a The NELAC Institute (TNI) Accrediting Body (AB). Region 10 is commended for participating in the TNI AB evaluation of ORELAP. However, since Region 10 and the OGWDW assessment team have expressed concern that the AB evaluation had a broad focus, we encourage Region 10 to conduct a supplemental review of its own, with a more particular focus on the drinking water portion of the ORELAP program. This is clearly within Region 10's authority and it helps Region 10 ensure that Oregon is meeting its primacy conditions.

Region 10 also sends annual questionnaires to the state laboratory certification programs. Region 10 has developed an SOP titled "Standard Operating Procedure for the Evaluation of State/Tribal Drinking Water Certification Programs," which clearly defines the process of evaluating the state certification programs. The SOP also clearly defines the qualifications necessary to become a CO in Region 10, including a requirement for maintaining bench analysis proficiency in the area in which the CO is auditing laboratories. The OGWDW assessment team inquired about how the state COs are maintaining this requirement, and found that COs sometime come to the Region 10 laboratory in Port Orchard (in fact, a CO from Alaska was visiting the Region 10 laboratory while this assessment was being conducted). The OGWDW assessment team finds this practice to be very beneficial for the certification programs in Region 10, as it is important for COs to be aware of method requirements and to be able to provide sound technical assistance and advice to laboratories during on-site assessments. The Idaho Bureau of Laboratories has also offered laboratory facilities and training for state COs from states within

Region 10, and Region 10 asked for suggestions on how to have EPA endorse this practice, or at least have some EPA oversight of the training.

Regional Certification Program Files

The OGWDW assessment team reviewed files from the four Region 10 states and one Tribal laboratory. The files contained older documents which could be archived, and duplicates that could be discarded. In general, the paper files could use some reorganization so that documents are more easily found. In addition, the assessment team had difficulty finding copies of newer on-site assessment reports and related documents. Region 10 has developed a formal document management system, using an MS Access database to track certification related reports and letters. While this is a very valuable tool, the assessment team had limited access to the database. As certification documents are moved from being kept in paper files to the electronic format, we ask that Region 10 make the database and the documents available to the next assessment team for a thorough review.

The OGWDW assessment team recommends that, for consistency, all state files contain key documents (i.e.: communication regarding onsite evaluation, notes from audit, final report, and laboratory response/corrective actions). The team also recommends that the Region 10 laboratory certification team keep records of technical direction that may occur between the Region and the state/territory. Any communication that requires interpretation of policy or policy determination should be kept as a record, as the documentation may be needed to verify the information and assist in future discussions. If these records are to be kept electronically, a guide should be developed for the assessment team to assist them in locating key certification documents for review.

Communications with State Counterparts

Region 10 is commended for having open lines of communications with their states. The OGWDW assessment team found that the states feel comfortable asking Region 10 questions. Region 10 communicates with each state individually during their annual certification program reviews. However, there is no annual meeting with all of the states together, as suggested in the MCLADW. Due to travel constraints, it is not typically feasible for many of the states in Region 10 to participate in an annual onsite meeting. However, OGWDW encourages all Regions, including Region 10, to conduct at least one annual meeting of all of the states/territories under their purview, with a teleconference being acceptable. OGWDW believes that such meetings serve to foster an environment of communication and respect, which serve to strengthen the certification programs of the states. OGWDW will participate in such meetings when possible.

Resources

Region 10 is commended for supporting the drinking water laboratory certification program through both personnel and travel resources. The OGWDW assessment team believes this support encourages and maintains a strong laboratory certification program both within the Region, and among the state programs. There were no findings or recommendations in this area.

FINDING:

- 40 CFR 142.10(b)(4) requires “assurance of the availability to the State of laboratory facilities certified by the Administrator and capable of performing analytical measurements of all contaminants specified in the State primary drinking water regulations”. None of the states in Region 10 have a PSL available for asbestos or radiochemistry. Region 10 should continue to work with the states to find PSL capability for radiochemistry and asbestos and should advise TSC when arrangements have been established.

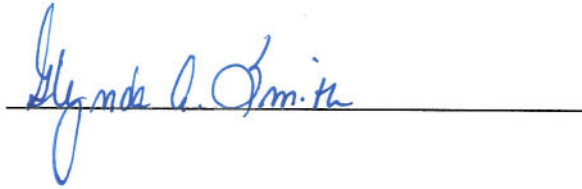
RECOMMENDATIONS:

- The Region 10 laboratory certification team should obtain the TNI on-site assessment reports and PT results from the commercial laboratories acting as part of the PSL network for Region 10 states, since those assessments and PTs support Region 10’s determination that the laboratories are operating appropriately. If obtaining that documentation is problematic, we suggest Region 10 work with the EPA Liaison to TNI, Arthur Clark in Region 1, to get copies for the files.
- Region 10 is encouraged to conduct a “supplemental” review (i.e., supplementing TNI’s AB evaluation) of the drinking water certification program for Oregon (ORELAP), as Region 10 is responsible for determining if the certification programs for primacy states meet the requirements of SDWA.
- The Region 10 laboratory certification team is encouraged to go through all state files and archive any files/documents no longer needed on-site and discard duplicates to allow for better records management. Paper files should be reorganized so that documents are more readily accessible.
- The Region 10 laboratory certification program should ensure that all files are complete and that all files consistently contain key documents (i.e.: communication regarding onsite evaluation, notes from audit, final report, and laboratory response/corrective actions). Additionally, any technical direction with the state laboratories/programs should be documented and maintained in the files, particularly if involving any type of policy determination/statement.
- Region 10 is also encouraged to hold annual meetings (face-to-face or via teleconference) with all of the states in their Region to foster an environment of communication and respect and to share information, both between the Region and states and among the states.

Submitted January 26, 2011

A handwritten signature in blue ink, reading "Michella S. Karapondo", written over a horizontal line.

Michella S. Karapondo, OGWDW, TSC

A handwritten signature in blue ink, reading "Glynda A. Smith", written over a horizontal line.

Glynda A. Smith, Ph.D., OGWDW, TSC